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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

HORIZON PHARMA IRELAND LIMITED,
HZNP LIMITED and HORIZON PHARMA
USA, INC.,

Plaintiffs,

v.

TELIGENT, INC., f/k/a IGI
LABORATORIES INC.

Defendant.

CIVIL ACTION No.
Document Filed Electronically

**COMPLAINT FOR
PATENT INFRINGEMENT**

COMPLAINT

Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc. (collectively, “Plaintiffs”), by their undersigned attorneys, bring this action against Teligent, Inc. (“Defendant” or “Teligent”), and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising from Defendant’s filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to market a generic version of Plaintiffs’ pharmaceutical product PENNSAID® (diclofenac sodium topical solution) 2% w/w (“PENNSAID® 2%”) prior to the expiration of United States Patent Nos. 9,220,784 (“the ’784 patent”) which covers PENNSAID® 2% and its use.

THE PARTIES

2. Plaintiff Horizon Pharma Ireland Limited is a corporation organized and existing under the laws of Ireland, with a principal place of business at Adelaide Chambers, Peter Street, Dublin 8, Ireland.

3. Plaintiff HZNP Limited is a nonresident Irish company that is a tax resident of Bermuda, with a principal place of business at 21 Laffan St., Hamilton, Pembroke, Bermuda HM09.

4. Plaintiff Horizon Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 520 Lake Cook Road, Suite 520, Deerfield, Illinois.

5. On information and belief, Defendant Teligent is a corporation organized under the laws of the state of Delaware, having its principal place of business at 105 Lincoln Avenue, Buena, New Jersey 08310.

6. On information and belief, Teligent was formerly known as IGI Laboratories Inc. This change of name was effective in or about November 2015.

7. On information and belief, Teligent is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this judicial district, through its own actions and through the actions of its agents and subsidiaries.

8. On information and belief, Teligent is registered with the State of New Jersey, Division of Revenue and Enterprise Services, as Entity No. 0100187002.

9. On information and belief, Teligent has offices, laboratory and manufacturing facilities located at 105 Lincoln Avenue, Buena, New Jersey 08310.

10. On information and belief, Teligent currently markets within the US, and in this judicial district, generic topical pharmaceutical products.

11. On information and belief, Teligent submitted to the FDA ANDA No. 208248 (“the Teligent ANDA”) for diclofenac sodium topical solution 2% w/w (“the Teligent Product”), continues to seek FDA approval of that application, and intends to participate in the commercial manufacture, marketing, offer for sale and sale of the Teligent Product throughout the United States, including in the State of New Jersey, in the event the FDA approves Teligent’s ANDA.

12. On information and belief, should the Teligent ANDA be finally approved by FDA, Teligent will sell, offer for sale and distribute the Teligent Product throughout the United States, including within this judicial district.

JURISDICTION AND VENUE

13. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

14. This Court has personal jurisdiction over Teligent by virtue of, *inter alia*, the fact that its principal place of business is in New Jersey, having conducted business in New Jersey, having availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being haled into court in this judicial district, and having engaged in systematic and continuous contacts with the State of New Jersey through the marketing and sales of generic drugs throughout the United States, and in particular within this judicial district, through the receipt of revenue from the sales and marketing of generic drug products, including Teligent products, within this judicial district, and through its intent to market and sell the Teligent Product, if approved, to residents of this judicial district.

15. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PATENTS-IN-SUIT

16. On October 27, 2015, the U.S. Patent and Trademark Office (“USPTO”) duly and legally issued the ’784 patent entitled “Diclofenac Topical Formulation.”

17. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the ’784 patent, which discloses and claims, *inter alia*, topical formulations and methods for treating pain in a knee due to osteoarthritis by administering a topical formulation to the knee twice daily. A true and correct copy of the ’784 patent is attached hereto as Exhibit A.

PENNSAID® 2%

18. Horizon Pharma Ireland Limited is the owner of FDA-approved New Drug Application No. 204623 (“the PENNSAID® 2% NDA”) for diclofenac sodium topical solution 2% w/w (PENNSAID® 2%), which is sold by Horizon Pharma USA, Inc. in the US under the tradename PENNSAID®.

19. The PENNSAID® 2% solution is currently approved by the FDA for the relief of pain of osteoarthritis of the knees.

20. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '784 patent was submitted to FDA for listing on December 29, 2015, and is listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") for the PENNSAID® 2% NDA.

21. The '784 patent covers PENNSAID® 2% and FDA-approved uses.

Teligent'S ANDA

22. On information and belief, Teligent submitted the Teligent ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market diclofenac sodium topical solution 2% w/w. On information and belief, the Teligent ANDA seeks approval to market the Teligent Product for the relief of pain of osteoarthritis of the knees.

23. On information and belief, the Teligent ANDA refers to and relies upon the PENNSAID® 2% NDA and contains data that, according to Teligent, demonstrate the bioequivalence of the Teligent Product and PENNSAID® 2%.

24. On information and belief, Teligent forwarded, via certified mail/registered mail, a letter dated March 24, 2015, to the following sole addressee: "Timothy Patrick Walbert, Director, HZNP Limited, Riverside One, Sir John Rogerson's Quay, Dublin 2, Ireland" ("the March 24th Letter"). The March 24th Letter stated that Teligent included a certification in the Teligent ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, U.S. Patent 8,563,613 ("the '613 patent") is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the Teligent Product (the "Paragraph IV Certification").

25. The Teligent ANDA seeks approval to engage in the commercial manufacture, use or sale of diclofenac sodium topical solution 2% before the expiration of the '613 patent.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 9,220,784

26. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-25 of this Complaint.

27. The '784 patent issued on December 29, 2015, and will expire no earlier than October 17, 2027.

28. Defendants have previously filed a Paragraph IV Certifications in the Teligent ANDA seeking approval to market the Teligent Product prior to the expiration of, *inter alia*, the '613 patent, which expires on October 17, 2027. Because the '784 patent also expires no earlier than October 17, 2027, Defendants seek approval of the Teligent ANDA, and to market the Teligent Product, prior to the expiration of the '784 patent.

29. By submitting and seeking approval of the Teligent ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Teligent Product, prior to date on which the '784 patent expires, Defendants have infringed the '784 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

30. Defendants' commercial manufacture, use, offer to sell, or sale of the Teligent Product within the United States, or importation of the Teligent Product into the United States, during the term of the '784 patent, also would infringe the '784 patent under 35 U.S.C. § 271(a), (b) and/or (c).

31. Upon approval of the Teligent ANDA, and commercialization of the Teligent Product, Defendants will actively induce and/or contribute to infringement of the '784 patent.

32. Upon information and belief, Defendants had actual and constructive notice of the '784 patent as of its issue date, and Defendants' infringement of the '784 patent is willful.

33. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Teligent's ANDA be a date that is not earlier than the expiration of the '784 patent, or any later expiration of any exclusivity or extension of the '784 patent to which Plaintiffs or the patent may become entitled.

34. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '784 patent.

35. Plaintiffs have no adequate remedy at law.

36. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT II FOR DECLARATION OF INFRINGEMENT OF
U.S. PATENT NO. 9,220,784

37. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-36 of this Complaint.

38. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

39. There currently exists an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

40. Defendants' commercial manufacture, use, offer to sell, or sale of the Teligent Product within the United States, or importation of the Teligent Product into the United States, during the term of the '784 patent, would infringe the '784 patent.

41. Defendants seek approval of the Teligent ANDA, and to market the Teligent Product, prior to the expiration of the '784 patent.

42. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import the Teligent Product prior to the expiration of the '784 patent.

43. Plaintiffs are entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of the Teligent Product prior to

the expiration of the '784 patent by Defendants would constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '784 patent.

44. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '784 patent.

45. Plaintiffs have no adequate remedy at law.

46. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Defendants, and respectfully request the following relief:

A. A judgment declaring that Defendants have infringed and will infringe one or more claims of the '784 patent;

C. A declaration pursuant to 28 U.S.C. § 2201 that if Defendants, their officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, manufacture, use, offer to sell, or sell the Teligent Product within the United States, or import the Teligent Product into the United States, prior to the expiration date of the '784 patent, it will constitute an act of infringement of the '784 patent;

E. If Defendants commercially manufacture, use, offer to sell, or sell the Teligent Product within the United States, or import the Teligent Product into the United States, prior to the expiration of the '784 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

G. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Teligent ANDA shall be a date not earlier than the expiration date of the '784 patent, inclusive of any extensions;

I. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

- J. Costs and expenses in this action; and
- K. Such other and further relief as the Court deems just and proper.

Date: February 5, 2016

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc., by their undersigned attorneys, hereby certify pursuant to Local Civil Rule 11.2 that the matter in controversy is the subject of the following pending actions:

- *Horizon Pharma Ireland Limited, et al. v. Actavis Laboratories UT, Inc.*, Civil Action No. 14-cv-07992-NLH-AMD (D.N.J.);
(Consolidated with Civil Action Nos. 1:15-cv-5025, -6131, and -6989);
- *Horizon Pharma Ireland Limited, et al. v. Actavis Laboratories UT, Inc.*, Civil Action No. 15-cv-7742-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. Teligent, Inc. f/k/a IGI Laboratories, Inc.*, Civil Action No. 1:15-cv-03508-NLH-AMD (D.N.J.)
(Consolidated with Civil Action Nos. 1:15-cv-5022, -6134 and -6991);
- *Horizon Pharma Ireland Limited, et al. v. Teligent, Inc. f/k/a IGI Laboratories, Inc.*, Civil Action No. 1:15-cv-07744-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. Lupin Limited, et al.*, Civil Action No. 15-cv-03051-NLH-AMD (D.N.J.)
(Coordinated with Civil Action Nos. 1:15-cv-5027 and -6935);
- *Horizon Pharma Ireland Limited, et al. v. Lupin Limited, et al.*, Civil Action No. 15-cv-07745-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. Amneal Pharms. LLC*, Civil Action No. 15-cv-03367-NLH-AMD (D.N.J.)
(Consolidated with Civil Action Nos. 1:15-cv-5024, -6990 and -6132);
- *Horizon Pharma Ireland Limited, et al. v. Amneal Pharms. LLC*, Civil Action No. 15-cv-07743-NLH-AMD (D.N.J.).

Respectfully submitted,

Date: February 5, 2016

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